

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

<p>In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation</p> <p>This Document Relates to: All Actions</p>	<p>MLD No. 15-2666 (JNE/FLN))</p> <p><b>DEFENDANTS’ RESPONSE TO PLAINTIFFS’ OBJECTION TO MARCH 23, 2018 ORDER REGARDING CONTINUED SEALING</b></p>
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Plaintiffs’ objection to Judge Noel’s March 23, 2018 Order Regarding Continued Sealing should be overruled. Plaintiffs’ objection is yet another attempt to put into the public domain out-of-context documents that have not been admitted into evidence at trial or relied upon by the Court in connection with any ruling in these proceedings.

Plaintiffs’ motion is purportedly motivated by their concern for the “public right to access” to Defendants’ documents. In reality, Plaintiffs’ motion is primarily intended to provide fodder for Scott Augustine’s public relations smear campaign against Defendants and the Bair Hugger system. As the Court is aware, the Kennedy Hodges law firm – a member of the Plaintiffs’ Executive Committee in these proceedings – has worked hand-in-glove with Augustine since 2009 to foment litigation, spread negative publicity, and cause competitive harm to Defendants. Whenever documents are unsealed in these proceedings, Augustine routinely blasts an email to his list of thousands of doctors and hospitals with his (misleading) spin on what the documents purportedly reveal. Defendants’ employees are then forced to spend extensive time responding to Augustine’s latest misrepresentation of the facts. Indeed, within 24 hours of the *Gareis* verdict,

Augustine offered answers to “questions” purportedly raised about the verdict. (*See* Ex. 1 to the Declaration of Monica L. Davies (“Davies Decl.”).) According to Augustine, Mr. Gareis’s claim was “[n]ot at all” typical of other cases in the MDL, and “[t]he plaintiff’s lawyers were only able to use a small fraction of the evidence available to them” because the Court “severely restricted evidence to what was known at the time of the surgery.” (*See id.* at 1-2.) Augustine would like nothing more than to publicize such “evidence” – including Defendants’ confidential documents – regardless of this Court’s rulings as to whether any of the documents at issue are relevant to any plaintiff’s claim.

Magistrate Judge Noel’s determination that the documents at issue in Plaintiffs’ motion should remain under seal was correct. Plaintiffs’ effort to publicize inadmissible, out-of-context documents to harm Defendants in the public arena – all while additional bellwether cases are being prepared for trial – is precisely why the rules allow confidential documents to be maintained under seal. Magistrate Noel’s March 23, 2018 Order should be affirmed. *See* L.R. 72.2(a) (a magistrate’s order may be set aside only where it is “clearly erroneous or contrary to law”).

## **ARGUMENT**

### **I. THE DOCUMENTS AT ISSUE ARE APPROPRIATELY DESIGNATED AS CONFIDENTIAL AND SHOULD REMAIN UNDER SEAL.**

The documents at issue, many of which were submitted in connection with Plaintiffs’ unsuccessful motion to add a claim for punitive damages and/or in opposition to Defendants’ case-specific motion for summary judgment in the *Gareis* matter, fall into one or more of the following categories:

**1. Sales Data and Strategy.** These documents include confidential sales data, communications between sales personnel concerning sales strategy, documents reflecting customer communications (including notes for strategies pertaining to specific accounts), and talking points for sales representatives. (*See* ECF Nos. 780, 803, 879, 887, 900, 91, 903, 905, 93, 940, and 942 (sealed documents); *see also* ECF Nos. 1002, 1003, and 1008 (Joint Motions Regarding Continued Sealing).)

**2. Scientific and Technical Data/Planning.** These documents reflect internal scientific and technical discussions, deliberations on proposed research, ideas for possible future product development, and the design and development of a next-generation Bair Hugger warming system not at issue in these proceedings. (*See* ECF Nos. 879, 891, 895, 900, 92, 924 at 98-100, 924 at 245, 929, 935, 940, 942 at 93-94, 945, 948 at 93-94, 948 at 96, 948 at 98-100, and 948 at 245 (sealed documents); *see also* ECF Nos. 1002, 1008, and 1011 (Joint Motions Regarding Continued Sealing).)

**3. Strategic Planning and Responses to Augustine Misrepresentations.**

These documents reflect testimony and internal deliberation regarding strategies to deal with customer perceptions influenced by the Augustine campaign, responses to efforts by Augustine to convince customers to switch from the Bair Hugger system to the HotDog, and responses to false statements by Augustine. (*See* ECF Nos. 789, 866, 868, 879, 881, 883, 915, 918, 924 at 318-22, 925, 944, and 948 at 318-22 (sealed documents); *see also* ECF Nos. 1002, 1006, 1008, 1009, and 1011 (Joint Motions Regarding Continued Sealing).)

These documents are confidential and appropriately kept under seal, as they reveal strategic planning information of competitive significance, the public disclosure of which would subject 3M to competitive harm. Moreover, Magistrate Judge Noel previously determined (prior to his March 23, 2018 Order) that several of the documents at issue should remain under seal (*see* ECF No 854) with no further objection from Plaintiffs. Plaintiffs should not be heard to challenge the confidentiality of those documents now.

**II. THE DOCUMENTS ARE NOT SUBJECT TO THE PUBLIC'S QUALIFIED RIGHT OF ACCESS BECAUSE THEY HAVE NOT PLAYED ANY SIGNIFICANT ROLE IN THE ADJUDICATIVE PROCESS.**

“[N]ot all documents filed by parties are ‘judicial records’; instead, only those documents that are *relevant to and integrally involved* in the resolution of the merits of a case are judicial records to which the presumption of public access attaches.” *Krueger v. Ameriprise Financial, Inc.*, No. 11-2781 (SRN/JSM), 2014 WL 12597948, at \*9 (D. Minn. Oct. 14, 2014) (emphasis added); *see also In re Application for an Order Pursuant to 18 U.S.C. Section 2703(D)*, 707 F.3d 283, 290 (4th Cir. 2013) (“[D]ocuments filed with the court are ‘judicial records’ *if they play a role in the adjudicative process*, or adjudicate substantive rights”) (emphasis added); *United States v. Amodeo*, 44 F.3d 141, 145 (2d Cir. 1995) (“[T]he item filed must be relevant to the performance of the judicial function and useful in the judicial process in order for it to be designated a judicial document.”), *rev’d in part on other grounds by United States v. Amodeo*, 71 F.3d 1044 (2d Cir. 1995); *United States v. El-Sayegh*, 131 F.3d 158, 163 (D.C. Cir. 1997) (“[W]hat makes a document a judicial record and subjects it to the common law right of access is the role it plays in the adjudicatory process.”). In other words, it is only those documents that “play a relevant

and useful role in the adjudication process” to which the public right of access attaches. *In re Policy Mgmt. Systems Corp. v. Ernst & Young*, 67 F.3d 296 (table), 1995 WL 541623, at \*3-4 (4th Cir. Sept. 13, 1995).

The documents at issue here do not fit these criteria. Although Plaintiffs have repeatedly referred to the documents as so-called evidence of Defendants’ purported knowledge of risk associated with the Bair Hugger system and other negative “facts” they believe support their claims, there is nothing to indicate that the documents have played any significant role in the adjudication of any plaintiff’s claims. They have not been cited or relied upon in connection with this Court’s rulings, whether on general or case-specific Daubert or dispositive motions. Moreover, the documents were excluded as evidence in the recent *Gareis* trial, and thus had no bearing on the jury’s deliberations or verdict. There is no basis on which even a qualified right of access should attach, therefore, and no basis on which the documents should be unsealed.<sup>1</sup>

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<sup>1</sup> Plaintiffs argue that any confidentiality protection otherwise afforded to Defendants was destroyed by the fact that Plaintiffs chose to display snippets from some of the documents in open court proceedings. (See ECF No. 1260 at 9.) The single case they cite is inapposite, however, as it addressed the confidentiality of trade secret information which, due to the nature of the information and protection claimed, was obviated by the use and discussion of the trade secrets in open court. *See In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, 245 F.R.D 632, 634 (D. Minn. 2007). Here, by contrast, it is not any trade secret status of the documents that warrants protection, but rather the obvious competitive harm that Defendants would incur if the documents are unsealed. That risk does not vanish simply because selected excerpts of the documents were briefly displayed on a screen at a hearing. Indeed, if Plaintiffs’ selected presentation of such snippets were a sufficient basis on which to unseal a document, Plaintiffs could unilaterally strip Defendants of any protection whatsoever, simply by quoting or displaying a document at their discretion. Such a result would effectively make it impossible for litigants to protect their confidential information.

**III. EVEN ASSUMING A QUALIFIED RIGHT OF PUBLIC ACCESS EXISTS, IT IS OUTWEIGHED BY DEFENDANTS' INTERESTS IN MAINTAINING THE CONFIDENTIALITY OF THE DOCUMENTS AT ISSUE.**

For the reasons set forth above, the confidential documents at issue are not appropriately considered “judicial documents” and, thus, there is no basis on which they should be subject to a qualified right of public access. Even assuming such a right exists, however, it is outweighed by Defendants’ interests in maintaining the confidentiality of the documents.

First, the documents are appropriately designated as confidential because they reflect (1) sales data and strategy, (2) scientific and technical data/planning, and (3) strategic planning and responses to Augustine’s misrepresentations. (*See infra* at 3-4.) Defendants face a very real threat of competitive harm if the documents are unsealed, which is not obviated by the fact that many of the documents were created several years ago. To this day, Augustine continues his campaign to publicly disparage 3M and the Bair Hugger system. He has taken every opportunity to publicly spread misinformation to 3M’s customers and potential customers, even going so far as to initiate an email blast claiming that 3M faces upwards of \$20 billion in damages – “most of it from punitive damages” – despite the fact that Plaintiffs’ motion to add a claim for punitive damages was denied shortly thereafter, in a decision affirmed by this Court. The only thing preventing him from using confidential documents to further misinform healthcare providers about Defendants and the Bair Hugger system is the protection afforded by this Court and the maintenance of confidential documents under seal. *See Nixon v. Warner Commc’ns, Inc.*, 435 U.S. 589,

598 (1978) (recognizing that “access has been denied where court files might have become a vehicle for improper purposes,” and that the court has power “to insure that its records are not used to gratify private spite or promote public scandal” or “as sources of business information that might harm a litigant’s competitive standing”) (internal citations omitted). Under such circumstances, it is critical that the Court make its determination “*in light of the relevant facts and circumstances of [this] particular case.*” *Id.* at 599 (emphasis added).

There is little – if any – public interest in making Defendants’ confidential documents available to the public, as they have not played any meaningful role in the adjudicative processes of this Court or the *Gareis* jury. Conversely, Defendants have a strong interest in maintaining the confidentiality of documents that have already been taken out of context, and that will surely be the subject of a new misinformation campaign if Augustine is given the opportunity. Defendants have submitted specific examples of Augustine’s ongoing use of materials produced in discovery to attack 3M and the Bair Hugger system. (See ECF No. 1235 at 5-6; ECF No. 1236, Exs. 1-2.) The risk of serious competitive harm faced by Defendants, together with the ongoing preparation for additional bellwether trials, support the decision to keep the documents at issue under seal. See, e.g., *Krueger*, 2015 WL 224705, at \*4 n.4 (among factors to be considered when determining whether to seal documents is the possibility of prejudice to those opposing disclosure) (citing *Schedin v. Ortho-McNeil-Janssen Pharms., Inc.*, No. 08-5743 (JRT), 2011 WL 1831597, at \*1-2 (D. Minn. May 12, 2011) (relevant factors that inform the decision of whether documents should be sealed include “minimiz[ing] the danger of an

unfair trial by adverse publicity”)) (internal citations omitted). Under the unique facts and circumstances of *this* case, it is clear that Defendants’ interests in maintaining the confidentiality of the documents outweigh any qualified right of public access that may otherwise exist.<sup>2</sup>

#### **IV. MAINTAINING THE SEAL OVER CONFIDENTIAL DOCUMENTS IS NOT CONTRARY TO PUBLIC HEALTH OR SAFETY.**

Finally, Plaintiffs argue that the Court should unseal the confidential documents at issue because they relate to “public health and safety.” (*See* ECF No. 1260 at 1.) Plaintiffs go so far as to claim that “[l]imiting the public access to these documents may prevent scientific research and effective precautions by the medical community.” (*Id.* at 2.) This argument bears no relationship to the documents themselves. This Court has already concluded that the documents do not show that Defendants knew or should have known of any purported risk that the Bair Hugger system causes periprosthetic joint infections – they can hardly be the missing spark for scientific research.

The basic premise of Plaintiffs’ argument – the idea that the safety of the Bair Hugger system has not been considered by the scientific and medical communities – is also unsupported. The safety and efficacy of the Bair Hugger system has been studied – and confirmed – time and time again. Indeed, the FDA directly addressed the allegations being made by Augustine and Plaintiffs in its August 30, 2017 safety communication to health

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<sup>2</sup> Plaintiffs also oppose Defendants’ objection to the unsealing of a draft prewarming report. (*See* ECF No 1260 at 9-10.) Defendants have addressed Plaintiffs’ arguments in their memorandum supporting their objection (*see* ECF No. 1258) and respectfully refer the Court to that document).



care providers, recognizing that “some health care providers and patients may be avoiding the use of forced air thermal regulating systems during surgical procedures due to concerns of a potential increased risk of surgical site infection (e.g., following joint replacement surgery).” (*See* ECF No. 751, DX1.) The FDA confirmed that, after collecting and analyzing the available data, it was “unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection.” (*Id.*) The FDA “remind[ed] health care providers that using thermoregulation devices during surgery, including forced air thermoregulating systems, have been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients.” (*Id.*) The FDA’s statements were consistent with other independent organizations that have reviewed the scientific data, as Defendants have established in prior briefing. (*See* ECF No. 762 at 17-20.)

The science will not miraculously tilt in their favor if Plaintiffs and Augustine are allowed to publicize cherry-picked excerpts of corporate documents that they believe cast Defendants in a negative light. Plaintiffs’ purported “public health and safety” concerns are no reason to reverse Magistrate Judge Noel’s March 23, 2018 Order.

### **CONCLUSION**

For all of the foregoing reasons, Plaintiffs’ objection to Magistrate Judge Noel’s March 23, 2018 Order should be overruled, and the Order should be affirmed. Defendants appropriately designated the documents as confidential, and Magistrate Judge Noel appropriately determined that the limited subset of documents should be kept under seal. In so ruling, Magistrate Noel rejected the reasons offered by Plaintiffs as to why the

documents should be unsealed, which are the same reasons they offer now. This Court should similarly reject Plaintiffs' arguments, and overrule their objection.

Dated: June 8, 2018

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